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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,424	07/11/2003	Alexis Borisy	50164/022002	3223

21559 7590 10/24/2005

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,424	BORISY ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-15,17-26,28,29 and 40-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-15,17-26,28,29 and 40-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-31-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 2, 5-15, 17-26, 28, 29 and 40-62 are presented for examination.

Applicants' amendment filed August 11, 2005 and the information disclosure statement filed August 31, 2005 have been received and entered.

Accordingly, the rejection made under 35 USC 112, second paragraph as set forth in the previous Office action dated February 9, 2005 at page 7 is hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 5, 7-9, 28, 29 and 40-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 and 35 of U.S. Patent No. 6,569,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are still generic to all that is recited in the claims of Patent No. 6,569,853. That is, the claims of the patent fall entirely within the scope of the claims of the present application, or in other words, claims 2, 5, 7-9, 28, 29 and 40-62

are anticipated by claims 1-24 and 35 of the patented application. Again, the patented application claims combination compositions containing chlorpromazine and pentamidine compounds and methods of using said compositions for treating neoplasms (leukemia, liver, colon, prostate, lung cancer, etc.), wherein the chlorpromazine and pentamidine compounds fall within claimed formulae (I) and (II).

Claims 2, 5, 7-9, 28, 29 and 40-62 are not allowed.

Claims 2, 5, 7-9, 28, 29 and 40-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,846,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are still generic to all that is recited in the claims of Patent No. 6,846,816. That is, the claims of the patent fall entirely within the scope of the claims of the present application, or in other words, claims 2, 5, 7-9, 28, 29 and 40-62 are anticipated by claims 1-13 of the patented application. Again, the patented application claims combination compositions containing chlorpromazine and pentamidine compounds and methods of using said compositions for treating neoplasms (leukemia, liver, colon, prostate, lung cancer, etc.), wherein the chlorpromazine and pentamidine compounds fall within claimed formulae (I) and (II).

Claims 2, 5, 7-9, 28, 29 and 40-62 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5-15, 17-26, 28, 29 and 40-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a neoplasm with a composition comprising components formula (I) and formula (II), wherein the neoplasm is lung cancer, does not reasonably provide enablement for the composition comprising formula (I) and formula (II) to treat other types of neoplasm or the addition of a third agent as disclosed in claims 17, 18, 45 and 46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

As of record, for reasons of record as set forth in the Office action dated February 9, 2005 at pages 4-7 as applied to claims 1-29 and 36-39.

Applicants' remarks regarding the instant specification do teach enablement for the composition comprising compounds of formula (I) and compounds of formula (II) to treat a neoplasm (lung cancer) is agreed by the Examiner. However, the instant specification does not contain any working examples showing the instant composition will treat other types of neoplasms as disclosed in claims 17, 18, 45 and 46. There are not working examples showing the addition of the third agent with the instant composition.

The rejection made under 35 USC 112, first paragraph is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 7-9, 11, 17-26, 28, 29 and 40-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dwivedi et al., "Effects of Treatment with Haloperidol, Chlorpromazine, and Clozapine on Protein Kinase C (PKC) and Phoshoinositide-Specific Phospholipase C (PI-PLC) Activity and on mRNA and Protein Expression of PKC and PLC Isozymes in Rat Brain", The Journal of Pharmacology and Experimental Therapeutica, 1999, Vol. 291, pp. 688-704. in view of Makulu et al. of PTO-1449 and further in view of Windholz et al., THE MERCK INDEX (1983), Tenth Edition, page 183, abstract no. 1308, all of record, for reasons of record as set forth in the previous Office action dated February 9, 2005 at pages 8-11 as applied to claims 1-11, 17-29 and 36-39.

Applicants' remarks regarding the prior art does not teach the instant combination of the components a) formula (I) , and b) formula (II) and further added c) a third agent are not persuasive since the instant rejection is based upon the well established principle of patent law that no invention resides in combining 2 or more ingredients of known character, where the results obtained are no more than the additive effects of the individual ingredients. It has not been demonstrated on the record, by means of experimental data commensurate in scope with the claimed subject matter that applicants' combination produces any unobvious or unexpected results. The mere arguments of applicants are insufficient to overcome the strong prima facie case of obviousness without the experimental data. Applicants' claims 2 and 28 containing component (b), formula (II) still reads on pentamidine.

The rejection made under 35 USC 103 is adhered to.

Claims 2, 7-9, 11, 17-26, 28, 29 and 40-62 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
October 20, 2005